DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Genesys Spine
Mr. William W. Sowers
Vice President of Quality and Regulatory
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

October 8, 2014

Re: K133245
Trade/Device Name: Genesys Spine Anterior Cervical Plate II System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 28, 2014
Received: August 29, 2014

Dear Mr. Sowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133245

Device Name
Genesys Spine Anterior Cervical Plate II System

Indications for Use *(Describe)*
The Genesys Spine Anterior Cervical Plate II System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

Submitter's Name:	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7080
Submitter's Fax:	800-817-4938
Contact Name:	William W. Sowers
Date Summary was Prepared:	28-Aug-14
Trade or Proprietary Name:	Genesys Spine Anterior Cervical Plate II System
Common or Usual Name:	Spinal Intervertebral Body Fixation Orthosis
Classification:	Class II per 21 CFR §888.3060
Product Codes:	KWQ
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Legally Marketed (unmodified) device:	Genesys Spine Anterior Cervical Plate System (Primary Predicate K111132), Synthes Anterior CSLP System (K000536 / K945700), Pioneer Aspect Anterior Cervical Plate System (K130427)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Anterior Cervical Plate II System will be offered in various device configurations based on surgical approach and patient anatomy, and will consist of a Genesys Spine cervical plate and screws that are inserted into the anterior surface of adjacent cervical vertebrae.

INDICATIONS FOR USE

The Genesys Spine Anterior Cervical Plate II System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or

dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

TECHNICAL CHARACTERISTICS

The Genesys Spine Anterior Cervical Plate II System is comprised of multiple sizes of plates and screws that are inserted into the anterior surface of adjacent cervical vertebrae. The device is applied after discectomy and insertion of autograft or allograft in the interbody space, and acts to stabilize the spine during fusion.

The plate components are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136. Additionally, cervical plates contain a securement tab component comprised of Nickel-Titanium (Nitinol) per ASTM F2063-00 to ensure that the screw is locked in place. The bone screws are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136.

PERFORMANCE DATA

The predetermined pass-fail criterion was that the mechanical test results for the Genesys Spine Anterior Cervical Plate II System be equivalent to (or greater than) previously cleared anterior cervical plate systems. Prior to performing mechanical testing, all possible configurations of the Anterior Cervical Plate II System construct were analyzed in order to determine the worst case to be used for testing. Static axial compression, static torsion, and dynamic axial compression testing in accordance with American Society for Testing and Materials (ASTM) F1717 "Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model" were then performed on the worst case Anterior Cervical Plate II System construct.
In addition, corrosion testing was performed in accordance with ASTM F2129

CONCLUSION

The overall technological characteristics and mechanical performance data lead to the conclusion that the Genesys Spine Anterior Cervical Plate II System is substantially equivalent to the Genesys Spine Anterior Cervical Plate System (K111132), the Synthes Anterior CSLP System (K000536 / K945700), and the Pioneer Aspect Anterior Cervical Plate System (K130427).